

OCT 29 1998

K983447

**510(k) Summary of Safety & Effectiveness**  
(as required by 21 CFR 807.92c)

**Date Prepared:**

25 September 1998

**Submitter's Information:**

Sectra Imtec AB  
Teknikringen 2  
SE-583 30 Linköping  
Sweden  
Phone: +1 46 13 23 52 00  
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**Trade Name, Common Name, Classification:**

Trade Name: WISE II Image Management System  
Common Name: Digital Imaging System  
Classification Name: System, Digital Image Communication, Accessory

**Predicate Device:**

Applicant: Sectra Imtec AB  
510(k) Number: K971451  
Device: WISE Image Management System

**Device Description:**

WISE II is a system for managing digital radiological images. This includes image storage and searching for images in archives and retrieving image for re-consultation. WISE II generally provides functions to:

- Access information related to requests, examinations and images
- Create, move, copy and delete folders and examination folders
- Add images to and delete images from examinations
- File examinations to the archives and retrieve examinations from the archives
- Retrieve examinations from DICOM conformant archives
- Manage images stored on multiple file servers
- Provide services (DICOM, WWW, etc) to clients via WISE gateways
- Interface RIS for relational integrity
- Send and retrieve images (teleradiology)

**Indications for Use:**

The Sectra AB WISE II Image Management System device is intended for the management and displaying of x-ray images, other radiological objects and information. It can manage images from different modalities, single and multiple file servers, and interfaces to various Radiological Information Systems (RIS), image storage and printing devices using DICOM or similar interface standards.

Typical users of this system are trained professionals including but not limited to physicians, radiologists, nurses, medical technicians, and assistants.

**Technological Characteristics:**

The WISE II system will run on Hewlett-Packard computers under HP-UX (Hewlett-Packard's version of Unix), SUN Micro System computers under SOLARIS (SUN's version of Unix), and on Windows NT operating systems for PCs, (as a minimum and depending upon system configuration).

**Performance Data:**

The subject and predicate devices both use standard data communications controls to detect errors. The subject device complies with IEC 950 – Safety of Information Technology Equipment, CISPR 22, class A – Electromagnetic Compatibility, IEC-801-2, IEC-801-3 – Electromagnetic Compatibility, IEEE 1003.1 – POSIX standard for Information Processing, FCC Part 15 sub-part B class A, IEEE 802.3 – Ethernet, LAN Interface Standard, ACR/NEMA Digital Imaging Communications In Medicine version 3.0.

**Conclusion:**

Similar to the predicate device, the WISE II System does not contact the patient, nor does it control any life sustaining devices. Images and information being reviewed, processed, relayed, and or transmitted are interpreted by a physician or trained medical personnel, providing ample opportunity for competent human intervention. The device and the predicate device share the same certification or conformance to performance standards and both function as Image Management Systems. Device failures, which might result in partial or failed transmissions, images, or data, may be recovered from storage or re-transmission after correcting the problem(s). Passwords are required for operation and to protect against unauthorized use.

Based on the information supplied in this 510(k), we conclude that the subject device is safe, effective, and substantially equivalent to the predicate device.

A handwritten signature in black ink, appearing to read 'Peter Andersson', with a long horizontal line extending to the right.

Peter Andersson  
Regulatory Assurance Manager  
Sectra Intec AB



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

OCT 29 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Herman Oosterwijk  
President  
c/o Otêch Inc.  
6741 Grant Lane  
Plano, TX 75024

Re: K983447  
Wise (II) Image Management System  
Dated: September 25, 1998  
Received: September 30, 1998  
Regulatory class: I  
21 CFR 892.2010/Procode: 90 LMB

Dear Mr. Oosterwijk:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

Lillian Yin, Ph.D.  
Director, Division of Reproductive,  
Abdominal, Ear, Nose and Throat  
and Radiological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

510(k) Number:

Device Name: WISE Image Management System

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓  
(Per 21 CFR 801.109)

OR

Over -The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)

David A. Segura  
(Division Sign-Off)  
Division of Reproductive, Abdominal, ENT,  
and Radiological Devices  
510(k) Number K983441